

CLINICAL RESEARCH PROTOCOL CONTINUING REVIEW APPLICATION	PROTOCOL NO. _____	PRINCIPAL INVESTIGATOR (Name, Institute/Branch, Address, Telephone): _____
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PROTOCOL TITLE: _____

ACTION REQUESTED:

- ☐ Renew -New subject accrual to continue
☐ Renew -Enrolled subject follow-up only
☐ Terminate -Protocol discontinued (describe briefly in the attached narrative.)

HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW?

- ☐ No
☐ Yes (Describe briefly in the attached narrative)

SUMMARY OF PROTOCOL SUBJECTS:

NIH	All Other Sites	
_____	_____	Accrual ceiling set by IRB
_____	_____	New subjects accrued since last review
_____	_____	Total subjects accrued since protocol began (If accrual has been less than expected, discuss in the attached narrative.)

REQUESTED ACCRUAL EXCLUSION (Check all that apply):

- | | |
|--|--|
| <input type="checkbox"/> None | <input type="checkbox"/> Asian |
| <input type="checkbox"/> Male | <input type="checkbox"/> Black or African American |
| <input type="checkbox"/> Female | <input type="checkbox"/> White |
| <input type="checkbox"/> Children | <input type="checkbox"/> Hispanic or Latino |
| <input type="checkbox"/> American Indian/ Alaskan Native | <input type="checkbox"/> Native Hawaiian or Pacific Islander |
| <input type="checkbox"/> Other: _____ | |

HAVE THERE BEEN ANY CHANGES IN THE SUBJECT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW?

- ☐ No
☐ Yes (Explain changes in the attached narrative)

HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW?

- ☐ No
☐ Yes (Explain changes in the attached narrative)

HAVE ANY UNEXPECTED COMPLICATIONS OR SIDE EFFECTS BEEN NOTED SINCE THE LAST REVIEW?

- ☐ No
☐ Yes (Identify and explain in the attached narrative)

HAVE ANY SUBJECTS WITHDRAWN FROM THIS STUDY SINCE THE LAST IRB APPROVAL?

- ☐ No
☐ Yes (Discuss in the attached narrative)

HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH, THAT MIGHT AFFECT THE IRB'S EVALUATION OF THE RISK/BENEFIT ANALYSIS OF HUMAN SUBJECTS INVOLVED IN THIS PROTOCOL?

- ☐ No
☐ Yes (Discuss in the attached narrative)

CHANGE IN PRINCIPAL INVESTIGATOR: ☐ No ☐ Yes

Delete: _____
 Add: _____

HAVE ANY ASSOCIATE INVESTIGATORS BEEN ADDED OR DELETED SINCE THE LAST REVIEW?

- ☐ No
☐ Yes (Identify all changes in the attached narrative.)

CHANGE IN LEAD ASSOCIATE INVESTIGATOR: ☐ No ☐ Yes

Delete: _____
 Add: _____

CHANGE IN MEDICAL ADVISORY INVESTIGATOR: ☐ No ☐ Yes

Delete: _____
 Add: _____

CHANGE IN RESEARCH CONTACT: ☐ No ☐ Yes

Delete: _____
 Add: _____

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET, etc.):

- ☐ None
☐ Medically indicated
☐ Research indicated (Complete NIH-88-23a, and attach to this application. Send a copy of entire protocol and NIH-88-23a to Chair, Radiation Safety for concurrent review).
☐ Research usage HAS NOT changed since originally approved by the IRB and RSC
☐ Research usage HAS changed since originally approved by the IRB and RSC (explain changes in the attached narrative)

INVESTIGATIONAL NEW DRUG/DEVICE: ☐ None ☐ IND ☐ IDE

FDA No. _____
 Name: _____
 Sponsor: _____

LIST ALL COMMERCIAL OR OTHER ENTITIES PROVIDING INVESTIGATIONAL DRUG/DEVICE:

HAVE ANY NON-NIH INVESTIGATORS OR SITES BEEN ADDED SINCE THE LAST REVIEW?

- ☐ No
☐ Yes (Identify the persons or sites and describe the collaboration in the attached narrative)

DOES THE PROTOCOL INVOLVE A DRUG/DEVICE/PRODUCT THAT MAY LEAD TO YOU OR THE NIH RECEIVING PAYMENT AND/OR ROYALTIES?

- ☐ No
☐ Yes (Append a statement of disclosure)

HAVE ANY INVESTIGATORS DEVELOPED EQUITY, CONSULTATIVE, OR OTHER FINANCIAL RELATIONSHIP WITH A NON-NIH SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST?

- ☐ No
☐ Yes (Append a statement of disclosure)

The Principal Investigator must attach to this application: (1) a copy of the current consent/assent documents and (2) a memorandum to the IRB Chair that addresses any "yes" responses to the above questions, and that includes a concise statement regarding protocol progress to date and reason(s) for continuing the study.

SIGNATURE	Principal Investigator	Print/Type Name	Date	Send to Accountable Investigator
RECOMMENDATION	Accountable Investigator	Print/Type Name	Date	Send to Branch Chief, or CC Dept. Head of PI
	Branch Chief or CC Dept. Head of P.I.	Print/Type Name	Date	Send to Clinical Director
APPROVALS	Clinical Director	Print/Type Name	Date	Send to Chair, Institutional Review Board
	Chair, For Institutional Review Board	Print/Type Name	Date	Send to Office of Protocol Services, through IRB Protocol Coordinator
COMPLETION	Protocol Specialist	Date		